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DOCKET NO.: P453.70115US01

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Sanghvi et al.  
Serial No.: 10/821,811  
Confirmation No.: Not Yet Assigned  
Filed: April 8, 2004  
For: PHARMACEUTICAL FORMULATION

Examiner: Not Yet Assigned  
Art Unit: Not Yet Assigned

## CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the 16 day of June, 2004.

Kristin J. Ketelhut  
Kristin J. Ketelhut

Commissioner For Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Transmitted herewith are the following documents:

[X] Information Disclosure Statement  
[X] PTO Form 1449 with cited references  
[X] Return Receipt Postcard

If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at (617) 646-8000, Boston, Massachusetts.

A check is not enclosed. If a fee is required, the Commissioner is hereby authorized to charge Deposit Account No. 23/2825. A duplicate of this sheet is enclosed.

Respectfully submitted,  
*Sanghvi et al., Applicant*

By: Edward R. Gates  
Edward R. Gates, Reg. No.: 31,616  
Wolf, Greenfield & Sacks, P.C.  
600 Atlantic Avenue  
Boston, Massachusetts 02210-2211  
Telephone: (617)646-8000

Docket No. P453.70115US01  
Date: June 16, 2004  
x07/08/04x



DOCKET NO: P0453.70115US01

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Kristin J. Ketelhut

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Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**STATEMENT FILED PURSUANT TO THE DUTY OF  
DISCLOSURE UNDER 37 CFR §§1.56, 1.97 AND 1.98**

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, the Applicant requests consideration of this Information Disclosure Statement.

**PART I: Compliance with 37 C.F.R. §1.97**

This Information Disclosure Statement has been filed within three months of the filing date of a National Application other than a continued prosecution application under 37 C.F.R. §1.53(d).

No fee or certification is required.

**PART II: Information Cited**

The Applicant hereby makes of record in the above-identified application the information listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

The Applicant hereby makes the following additional information of record in the above-identified application.

The Applicant would like to bring to the Examiner's attention the following co-pending applications that may contain subject matter related to this application:

<u>Docket No.</u>	<u>Serial No.</u>	<u>Filing Date</u>	<u>Inventor(s)</u>
P0453.70109US00	10/163,482	June 5, 2002	Moss et al.
P0453.70110US00	10/278,630	October 23, 2002	Foss et al.
<sup>1</sup> P0453.70110US01	10/779,129	February 12, 2004	Foss et al.
P0453.70112US01	10/821,813	April 8, 2004	Boyd et al.
P0453.70113US00	10/357,669	February 4, 2003	Foss et al.
<sup>2</sup> P0453.70113US01	10/779,128	February 12, 2004	Foss et al.
<sup>2</sup> P0453.70113US02	10/778,268	February 12, 2004	Foss et al.
<sup>2</sup> P0453.70113US03	10/785,320	February 12, 2004	Foss et al.
<sup>2</sup> P0453.70113US04	10/785,668	February 24, 2004	Foss et al.
P0453.70114US00	10/358,560	February 5, 2003	Foss et al.
P0453.70116US01	10/821,809	April 8, 2004	Sanghvi et al.

<sup>1</sup>Copy not enclosed; see P0453.70110US00, Serial No. 10/278,630 for identical specification

<sup>2</sup>Copy not enclosed; see P0453.70113US00, Serial No. 10/357,669 for identical specification

The following are remarks concerning the other information cited:

**PART III: Remarks**

Documents cited anywhere in the Information Disclosure Statement are enclosed unless otherwise indicated. It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application;
3. The citations for the information be printed on any patent which issues from this application.

By submitting this Information Disclosure Statement, the Applicant makes no representation that a search has been performed, of the extent of any search performed, or that more relevant information does not exist.

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

Notwithstanding any statements by the Applicant, the Examiner is urged to form his own conclusion regarding the relevance of the cited information.

An early and favorable action is hereby requested.

Respectfully submitted,  
Sanghvi et al., *Applicant*

By: Edward R. Gates  
Edward R. Gates, Reg. No. 31,616  
Wolf, Greenfield & Sacks, P.C.  
600 Atlantic Avenue  
Boston, Massachusetts 02210-2211  
Telephone: (617) 646-8000

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FORM PTO-1449/A and B (Modified)				APPLICATION NO.: 10/821,811	ATTY. DOCKET NO.: P0453.70115US01
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>				FILING DATE: April 8, 2004	CONFIRMATION NO.: Not Yet Assigned
				APPLICANT: Sanghvi et al.	
Sheet	1	of	6	GROUP ART UNIT: Not Yet Assigned	EXAMINER: Not Yet Assigned

## U.S. PATENT DOCUMENTS

Examiner's Initials	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication or of issue of Cited Document MM-DD-YYYY
		Number	Kind Code		
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A2	2002/0028825	A1		Foss, et al.	03-07-2002
A3	2001/0033865	A1		Oshlack, et al.	10-25-2001
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Examiner's Initials	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document (not necessary)	Date of Publication of Cited Document MM-DD-YYYY	Translation (Y/N)
		Office/Country	Number	Kind Code			
B1	AU	610,561			Shelley	08-17-1988	
B2	CA	1,315,689			The University of Chicago	04-06-1993	
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Sheet	2	of	6	

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B13	WO	95/31985	A2	Minoia, <i>et al.</i>	11-30-1995	
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B15	WO	98/25613		Klinge Pharma GmbH	06-18-1998	Yes
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#### OTHER ART – NON PATENT LITERATURE DOCUMENTS

Examiner's Initials	Cite No	Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
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Sheet	4	of	6	EXAMINER: Not Yet Assigned	

C42	KOOB et al., Effects of opiate antagonists and their quaternary derivatives on heroin self-administration in the rat. <i>J Pharmacol Exp Ther.</i> 1984 May;229(2):481-6.		
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C106	YUAN et al., Methylnaltrexone prevents morphine-induced delay in oral-cecal transit time without affecting analgesia: a double-blind randomized placebo-controlled trial. Clin Pharmacol Ther. 1996 Apr;59(4):469-75.		
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